

Exhibit P

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,

Plaintiff,

v

BIONPHARMA, INC.,

Defendant.

: CIVIL ACTION

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NO. 21-1286-LPS

Wilmington, Delaware
Wednesday, November 10, 2021
Oral Argument Hearing

BEFORE: HONORABLE LEONARD P. STARK, U.S.D.C.J.

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL, LLP
BY: MEGAN E. DELLINGER, ESQ.

and

WILSON SONSINI GOODRICH & ROSATI
BY: WENDY L. DEVINE, ESQ., and
KRISTINA M. HANSON, ESQ.
(San Francisco, California)

and

WILSON SONSINI GOODRICH & ROSATI
BY: NATALIE J. MORGAN, ESQ.
(San Diego, California)

Counsel for Azurity
Pharmaceuticals, Inc.

Brian P. Gaffigan
Official Court Reporter

1 APPEARANCES: (Continued)

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3 PHILLIPS McLAUGHLIN & HALL, P.A.
4 BY: MEGAN C. HANEY, ESQ.

5 and

6 TAFT STETTINIUS & HOLLISTER, LLP
7 BY: ROSHAN P. SHRESTHA, Ph.D., ESQ., and
8 ANDREW M. ALUL, ESQ.
9 (Chicago, Illinois)

10 Counsel on behalf of Bionpharma, Inc.

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23 P R O C E E D I N G S

24 (REPORTER'S NOTE: The following oral argument
25 hearing was held in open court, beginning at 1:01 p.m.)

1 in about an hour. I need about an hour. So I don't expect
2 to have any more questions for you.

3 I do think I'm going to be able to give you my
4 decisions on the motions that were argued today, so make
5 sure at least one representative of each side is here, but
6 you are free for about an hour.

7 We will be in recess until 4:00 o'clock.

8 (Recess taken at 3:04 p.m.)

9 * * *

10 (Proceedings reconvened at 4:00 p.m.)

11 THE COURT: Have a seat.

12 So as I indicated when we broke, I thought I
13 would be able to rule on the motions, and I am able to rule
14 on the motions. The argument today was very helpful from
15 all of you, so thank you for that.

16 Just preliminarily, I'll say there was reference
17 to my *Noven* decision. I'm familiar with it, but I had not
18 considered it in connection with today's decisions. It
19 wasn't in the briefing, and I assure you, I don't remember
20 it that well, and so I don't think it has influenced my
21 decisions.

22 So the request for any further briefing is denied.

23 So let me tell you my rulings, and then I will
24 try to explain the basis for them.

25 First, this is the order I'm going to largely

1 address the issues in:

2 Plaintiff's motion for a preliminary injunction
3 is denied.

4 Defendant's motion to dismiss is denied.

5 And then plaintiff's motion for leave to file an
6 amended complaint, which we didn't talk about today that is
7 pending, is granted.

8 So let me try to explain that.

9 First, on the preliminary injunction motion
10 which I have indicated is denied, as we all know a
11 preliminary injunction is an extraordinary remedy that
12 should be granted only in limited circumstances. And I'm
13 denying it here because principally, plaintiffs have failed
14 to show a likelihood of success on the merits.

15 I believe they have also failed to show that the
16 balance of harms and the public interest favor the relief
17 they're seeking, but I will principally talk about the issue
18 of likelihood of success on the merits.

19 The main reason that the plaintiffs have not
20 shown in my view a likelihood of success on the merits, in
21 fact, really the only reason is that defendants have raised
22 substantial questions of validity of the patents-in-suit.
23 And they have presented persuasive evidence to support at
24 least two of their invalidity defenses.

25 I'm not going to talk about infringement at

1 But turning to the other factors.

2 I'm going to assume that the plaintiffs have
3 shown irreparable harm. Even assuming that, I believe
4 the balance of harms does not favor the relief that the
5 plaintiffs seek under the circumstances here.

6 Those circumstances now include a defendant
7 competing in the marketplace against the plaintiff,
8 competing with the lower-priced generic drug product. The
9 price -- I'm sorry -- product that individual patients are
10 using and relying.

11 A product that the defendant had the right to
12 launch at the time that it launched, and notwithstanding
13 the later or the issue -- excuse me. Notwithstanding the
14 issuance of the '023 patent, the defendant had prevailed in
15 the first wave litigation, prevailed with a stipulation in
16 the second wave litigation, fought to become the first filer
17 and is now roughly halfway through enjoying the 180 day
18 exclusivity period.

19 And I believe under the totality of the
20 circumstances, even crediting what the plaintiffs have
21 contended that they have proven as irreparable harm, that
22 the defendant would be harmed more by my granting the
23 requested injunction than plaintiffs would be by my denying
24 the requested injunction.

25 Even if that were not the case, I turn to the

1 public interest. And I think under the circumstances here,
2 considering the totality of the circumstances, the public
3 interest does not support the requested injunction which,
4 again, would require the Court to remove from the market a
5 lower-priced generic drug product on which some number of
6 patients are relying.

7 I recognize that Azurity's motion implicates
8 numerous public interests, including the, of course, very
9 important public interest in enforcing patent rights and in
10 motivating the large investments that are required to fund
11 medical research and development of new medical products,
12 but there are competing public interests as well, including
13 providing for generic drugs, not enforcing patents that may
14 be nonvalid and promoting access to widespread access to
15 lower-cost medications.

16 To me, this is an issue that can only be
17 resolved on case-by-case basis. And I think the record
18 here, again, is not one that favors the relief sought by the
19 plaintiff.

20 So for all those reasons, the plaintiff's motion
21 for preliminary injunction is denied.

22 Let me turn to the defendant's motion to
23 dismiss, which I noted at the outset is also denied.

24 Bionpharma has moved to dismiss Azurity's
25 complaint on the basis of claim preclusion, arguing that

1 court.

2 THE COURT: Thank you very much. I'm sure
3 everybody wants to be on the same page as you, so I won't
4 make anybody else speak to it. But thank you very much for
5 that. We will be in recess.

6 (Hearing ends at 4:26 p.m.)

7
8 I hereby certify the foregoing is a true and accurate
9 transcript from my stenographic notes in the proceeding.

10 /s/ Brian P. Gaffigan
11 Official Court Reporter
12 U.S. District Court
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